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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|-----------------------|------------------|
| 10/663,352 | 09/15/2003 | Mingchih M. Tseng | 00216-091011 / OB-37H | 1599 |
| 26161 | 7590 | 06/16/2005 | | |
| FISH & RICHARDSON PC | | | EXAMINER | |
| 225 FRANKLIN ST | | | KRASS, FREDERICK F | |
| BOSTON, MA 02110 | | | ART UNIT | PAPER NUMBER |
| | | | 1614 | |

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/663,352 | TSENG ET AL. |
| | Examiner Frederick F. Krass | Art Unit 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 February 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 45-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 45-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Prior Rejections

Unless repeated infra, all prior rejections are withdrawn.

Informalities

Claim 48, second line, "comprising" is grammatically incorrect and should be amended to read ---
comprises ---

Anticipation Rejection

Claims 45-50 were rejected under 35 U.S.C. 102(b) as being anticipated by Barclay et al (USP 5,021,053).

This rejection is maintained and is now applicable to claims 45-52.

Newly added claim 52 recites a matrix comprising "a polystyrene". This limitation is met by the disclosure of "polystyrene derivatives" at col. 90, lines 27-29, and lines 51 and 52, as discussed in the previous Office action (p. 3, ¶ 1 therein).

Applicants state that they "do not understand why the Examiner believes components in two distinct layers qualify as 'a mixture' as required instantly". (Remarks, p. 3, ¶ 3). It is the examiner's position that Applicant is interpreting (as reflected by that remark) the term "mixture" in an unduly limiting manner, importing limitations into the term that are not present in the claim itself, nor required by the teachings of the instant specification.

Instant claim 45 recites a color-changing matrix "comprising" a layer "including" a "mixture" of water-insoluble, water-soluble polymer and a water-leachable colorant. There is nothing in the instant specification that requires "a layer" to comprise a single structure. As the term "layer" is typically used in the laminate art, it is inclusive of single layers which themselves further "include" combinations of multiple

sublayers. See for example the abstract of USP 4,701,404, which describes an individual layer ("each of said layers") which is "composed of a plurality of sub-layers". (This reference is cited herein only for factual exemplification, and not as substantive prior art).

Similarly, nothing in the instant specification requires that the water-insoluble polymer, water-soluble polymer, and water-leachable colorant be disposed in the same sublayer. A mixture of separate sublayers, each containing one of the polymers in question, forms a larger "layer" which contains the sublayers as a "mixture". Note also that the instant claim uses the open-ended term "comprising", which permits the inclusion of additional layers.

Moreover, although mixtures as claimed are implicitly disclosed, the term "mixture" does not appear to be explicitly used, and certainly is never defined, anywhere in the instant specification. Lacking such a definition, it is appropriate to interpret that term as broadly as is reasonable and to look to an extrinsic source for guidance.

Webster's Ninth New Collegiate Dictionary defines the term "mixture" as:

1(a) : the act, the process, or an instance of mixing **(b1)**: the state of being mixed **(b2)**: the relative proportions of constituents; *specif.* the proportion of fuel to air produced in a carburetor **2**: a product of mixing: COMBINATION as **a**: a portion of matter consisting of two or more components in varying proportions that retain their own properties **b**: a fabric woven of variously colored threads **c**: a combination of several different kinds. (Emphasis original).

Thus, a mixture can contain separate components in separate physical locations, as in a fabric made of various colored threads. The instant claims never require a homogenous mixture. Thus, in the same way, the multilayer structures of Barclay et al form "mixtures" of water-insoluble and water soluble polymers, even though they are not homogenously combined in the same sublayer. Indeed, this interpretation is entirely consistent with the teachings of the specification, which disclose as preferred embodiments matrices comprising two separate layers, joined together. See for example the passage bridging p. 4, line 27 to p. 5, line 5; p. 6, lines 1-13; and page 18, lines 10 et seq.

Newly added claim 51 recites a matrix which "includes over 50% of the water-insoluble polymer" by weight. Based on the above analysis, the osmotic device of the prior art, which is a "layer" comprising

sublayers of water-insoluble polymer, water-soluble polymer, and an outer semipermeable membrane layer also comprising a water-insoluble polymer, would certainly meet that limitation.

Action is Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614

